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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
BERTAGNA, ANGELA MARIE	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,102	NAKAKITA ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/30/08; 11/6/07; 10/22/07; 12/18/06; 7/5/06; 4/10/06.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claim 4, in the reply filed on December 22, 2008 is acknowledged. Linking claims 1 and 13 will also be examined with the elected group. Thus, claims 1, 4, and 13 are the subject of this Office Action.

Claims 2, 3, and 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 22, 2008.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. Applicant's submission of an Information Disclosure Statement on April 10, 2006, July 5, 2006, December 18, 2006, October 22, 2007, November 6, 2007, and July 30, 2008 is acknowledged. Signed copies are enclosed.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 are indefinite, because the structural requirements of the primer recited in independent claim 1 are unclear. Claim 1 is drawn to a primer for amplifying a region of an *Alicyclobacillus* 16S rDNA sequence that has two segments. Part (b) of claim 1 recites that the second segment of the primer has "a base sequence located at the 5' end of the first segment which is complementary to the nucleic acid sequence at the 3' end of the first segment". It is not clear from this recitation as to what sequence the second segment is complementary. In particular, it is not clear whether the second segment of the primer must be complementary to the 3' region of the first segment of the primer (*i.e.* the primer forms a loop via hybridization of the 5' second segment with the 3' first segment) or if the second segment of the primer must be complementary to a region of the target nucleic acid located 3' of the region to which the first segment of the primer anneals (*i.e.* the primer forms a loop via hybridization of the 5' second segment to a region produced upon polymerase-mediated extension of the first segment). Both interpretations have been considered with respect to the prior art.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously).

Claim 1 is drawn to a primer that amplifies a target region selected from a portion of the nucleotide sequence from base 81 to base 934 of the 16S rDNA of an *Alicyclobacillus* species. The primer has a first segment that anneals to the 16S rDNA sequence of the *Alicyclobacillus* species and a second segment that is located 5' of the first segment and is complementary to the nucleic acid sequence at the 3' end of the first segment.

Yamazaki teaches primers for amplifying *Alicyclobacillus acidoterrestris* by RT-PCR (abstract and page 351). The primers of Yamazaki are designed from the V2 and V4 regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence and amplify a region of the 16S rDNA sequence between nucleotides 81 and 934 (abstract, page 351, column 2, and Figure 1). The 190F primer of Yamazaki has a first segment (nucleotides 3-19) that anneals to the 16S rDNA sequence of *Alicyclobacillus acidoterrestris* and serves as a primer. The 190F primer of Yamazaki also has a second segment (AC) that is located 5' of the first segment and is complementary to the nucleic acid sequence at the 3' end of the first segment (GT) (page 351, column 2). As discussed above, the structural requirements of the second segment of the claimed primer are unclear, and the claim encompasses primers that have a 5' region that is

complementary to the 3' region of the primer. Thus, the prior art of Yamazaki anticipates the primer of claim 1.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al. (Journal of General Microbiology (2002) 48: 243-250; cited on an IDS).

Claim 1 is drawn to a primer that amplifies a target region selected from a portion of the nucleotide sequence from base 81 to base 934 of the 16S rDNA of an *Alicyclobacillus* species. The primer has a first segment that anneals to the 16S rDNA sequence of the *Alicyclobacillus* species and a second segment that is located 5' of the first segment and is complementary to the nucleic acid sequence at the 3' end of the first segment.

Goto teaches primers for amplifying *Alicyclobacillus* species (page 245, column 1). The R-1 primer of Goto is designed to amplify a region of an *Alicyclobacillus* 16S rDNA sequence between nucleotides 81 and 934 (page 245, column 1). The R-1 primer of Goto has a first segment that anneals to the 16S rDNA sequences (nucleotides 3-21) and a second segment (AC) that is located 5' of the first segment and is complementary to the nucleic acid sequence at the 3' end of the first segment (GT) (see page 245, column 1). As discussed above, the structural requirements of the second segment of the claimed primer are unclear, and the claims encompass primers that have a 5' region that is complementary to the 3' region of the primer. Thus, the prior art of Goto teaches a primer that meets the requirements of claim 1.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Notomi et al. (Nucleic Acids Research (2000) 28(12): e63; cited previously).

Claim 1 is drawn to a primer that amplifies a target region selected from a portion of the nucleotide sequence from base 81 to base 934 of the 16S rDNA of an *Alicyclobacillus* species.

Yamazaki teaches primers for amplifying *Alicyclobacillus acidoterrestris* by RT-PCR (abstract and page 351). The primers of Yamazaki are designed from the V2 and V4 regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence and amplify a region of the 16S rDNA sequence between nucleotides 81 and 934 (abstract, page 351, column 2, and Figure 1). The

primers of Yamazaki also have a first segment that anneals to the 16S rDNA sequence (see Figure 1 and page 351, column 2).

As discussed above, the structural requirements of the second segment of the claimed primer are unclear, and the claims as written encompass primers having a second segment that is located 5' of the first segment and is complementary to a region located 3' of the region to which the first segment of the primer anneals. Yamazaki does not teach a primer having a second segment with these features.

Notomi teaches methods for isothermal nucleic acid amplification (abstract, pages ii-iv, and Figure 1). Notomi teaches that the disclosed amplification method is more sensitive and specific than conventional PCR amplification (abstract and pages v-vi). The methods of Notomi are conducted using primers having a first segment that anneals to a target nucleic acid and a second segment that is complementary to a region 3' of the region to which the first segment anneals (Figures 1-2 and pages ii-iv).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to combine the teachings of Yamazaki and Notomi. An ordinary artisan would have been motivated to target the 16S rDNA sequence of *Alicyclobacillus* using a primer having a first segment as taught by Yamazaki and a second segment located 5' of the first segment and complementary to a region 3' of the first segment, since Notomi taught that primers having these features could be used to practice an isothermal amplification method that was more sensitive and specific than the PCR amplification method taught by Yamazaki. An ordinary artisan would have had a reasonable expectation of success in doing so, since Notomi provided extensive guidance regarding the design of primers having the claimed features (pages ii, iv, and v) and

since Yamazaki identified regions of the 16S rDNA from *Alicyclobacillus acidoterrestris* useful for primer design (page 351). Thus, the primer of claim 1 is *prima facie* obvious over Yamazaki in view of Notomi.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Nagamine et al. (Molecular and Cellular Probes (2002) 16: 223-229).

Claim 1 is drawn to a primer that amplifies a target region selected from a portion of the nucleotide sequence from base 81 to base 934 of the 16S rDNA of an *Alicyclobacillus* species.

Yamazaki teaches primers for amplifying *Alicyclobacillus acidoterrestris* by RT-PCR (abstract and page 351). The primers of Yamazaki are designed from the V2 and V4 regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence and amplify a region of the 16S rDNA sequence between nucleotides 81 and 934 (abstract, page 351, column 2, and Figure 1). The primers of Yamazaki also have a first segment that anneals to the 16S rDNA sequence (Figure 1 and page 351, column 2).

As discussed above, the structural requirements of the second segment of the claimed primer are unclear, and the claims as written encompass primers having a second segment that is located 5' of the first segment and is complementary to a region located 3' of the region to which the first segment of the primer anneals. Yamazaki does not teach a primer having a second segment with these features.

Nagamine teaches methods for isothermal nucleic acid amplification (abstract, pages 224-225, and Figures 1 & 3). Nagamine teaches that the disclosed amplification method has the

following advantageous properties: (i) high sensitivity, (ii) high specificity, (iii) the ability to amplify nucleic acids isothermally, and (iv) the elimination of the need for a denatured DNA template (page 223). The methods of Nagamine are conducted using primers having a first segment that anneals to a target nucleic acid and a second segment that is located 5' of the first segment and is complementary to a region 3' of the region to which the first segment of the primer anneals (pages 224-225 and Figures 1 & 3).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to combine the teachings of Yamazaki and Nagamine. An ordinary artisan would have been motivated to target the 16S rDNA sequence of *Alicyclobacillus* using a primer having a first segment as taught by Yamazaki and a second segment located 5' of the first segment and complementary to a region 3' of the first segment, since Nagamine taught that primers having these features could be used to practice an isothermal amplification method that was more sensitive and specific than the PCR amplification method taught by Yamazaki. An ordinary artisan would have had a reasonable expectation of success in doing so, since Nagamine provided guidance regarding the design of primers having the claimed features (pages 224-225) and since Yamazaki identified regions of the 16S rDNA from *Alicyclobacillus acidoterrestris* useful for primer design (page 351). Thus, the primer of claim 1 is *prima facie* obvious over Yamazaki in view of Nagamine.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Notomi et al. (Nucleic Acids Research (2000) 28(12): e63; cited previously) and further in view of Ahern (The

Scientist (1995) Vol. 9, 5 printed pages) **or** Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Nagamine et al. (Molecular and Cellular Probes (2002) 16: 223-229) and further in view of Ahern (The Scientist (1995) Vol. 9, 5 printed pages).

Claim 13 is drawn to a kit comprising a strand-displacing DNA polymerase, dNTPs, a reaction buffer and the primer of claim 1 or the primer set of claim 4.

The combined teachings of Yamazaki and Notomi **or** Yamazaki and Nagamine suggest the primer of claim 1, as discussed above.

Regarding claim 13, Yamazaki teaches conducting nucleic acid amplification using a DNA polymerase, dNTPs, and reaction buffer (page 351, column 2). Likewise, Notomi and Nagamine each teach conducting nucleic acid amplification using a DNA polymerase having strand displacement activity, dNTPs, and reaction buffer (pages ii-iv of Notomi and page 224 of Nagamine).

Yamazaki, Notomi, and Nagamine do not teach packaging the reagents used to conduct the nucleic acid amplification reactions in a kit.

Ahern teaches that kits comprising biochemical reagents provide a means of quality control and offer practitioners in the art savings of time and money (pages 3-4).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to package a reaction buffer, dNTPs, a DNA polymerase with strand displacement activity, and the primer suggested by the combined teachings of Yamazaki and Notomi or the primer suggested by the combined teachings of Yamazaki and Nagamine in a kit. An ordinary artisan would have been motivated to do so with a reasonable expectation of success, since Ahern taught that kits comprising biochemical reagents provided a means of quality control and

offered practitioners in the art savings of time and money (pages 3-4). Thus, the kit of claim 13 is *prima facie* obvious over Yamazaki in view of Notomi and further in view of Ahern **or** Yamazaki in view of Nagamine and further in view of Ahern.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Goto et al. (Journal of General Microbiology (2002) 48: 243-250; cited on an IDS) and further in view of Nagamine et al. (Molecular and Cellular Probes (2002) 16: 223-229).

Claim 4 is drawn to a primer set for detecting *Alicyclobacillus acidoterrestris* by amplification of its 16S rDNA sequence. The primer set comprises an oligonucleotide set consisting of the sequences set forth in SEQ ID NO: 9-13.

Yamazaki teaches primers for amplifying *Alicyclobacillus acidoterrestris* by RT-PCR (abstract and page 351). The primers of Yamazaki are designed from the V2 and V4 regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence (abstract, page 351, and Figure 1).

Yamazaki does not teach a primer set consisting of SEQ ID NO: 9-13.

Nagamine teaches methods for loop-mediated isothermal nucleic acid amplification (LAMP) (abstract, pages 224-225, and Figures 1 & 3). Nagamine teaches that the LAMP method has the following advantageous properties: (i) high sensitivity, (ii) high specificity, (iii) the ability to amplify nucleic acids isothermally, and (iv) the elimination of the need for a denatured DNA template (page 223). The LAMP method of Nagamine is conducted using six primers. Two of the primers (inner primers FIP and BIP) have a first segment that anneals to the target nucleic acid and a second segment that is complementary to a region of the extension

product produced by extension of the first segment (pages 224-225 and Figures 1 & 3). Two of the primers are outer primers that hybridize to the target nucleic acid upstream of the inner primers (pages 224-225 and Figures 1 & 3). Two of the primers are loop primers that anneal to the loop formed by the inner primers (pages 224-225 and Figures 1 & 3). Nagamine teaches that the loop primers accelerate the progress of the LAMP reaction (pages 224 and 226).

Goto analyzed the 16S rDNA sequences of a plurality of *Alicyclobacillus* species (abstract and pages 244-247). Goto identified regions of the 16S rDNA sequence that are conserved and variable between *Alicyclobacillus* species (abstract, pages 245-247, and Figure 2). Goto also discloses the 16S rDNA sequence of *Alicyclobacillus acidoterrestris* (Figure 1, where GenBank Accession Number AB059676 is taught). The instant SEQ ID NO: 11-13 are contained in this sequence. Also, the first and second segments of the instant SEQ ID NO: 9 and 10 are contained in this sequence.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to combine the teachings of Yamazaki, Nagamine, and Goto. An ordinary artisan would have been motivated by the teachings of Yamazaki and Nagamine to design and synthesize primers for amplifying *Alicyclobacillus acidoterrestris* that were suitable for use in the LAMP method taught by Nagamine. An ordinary artisan would have been motivated to do so, because Nagamine taught that the LAMP amplification method was more sensitive and specific compared to the conventional PCR amplification method taught by Yamazaki (page 223). Combining the teachings of Yamazaki and Nagamine would have suggested to the ordinary artisan a primer set for amplifying the 16S rDNA sequence of *Alicyclobacillus acidoterrestris* having six primers – two outer primers, two inner primers, and two loop primers

(see Figures 1 and 3 of Nagamine). An ordinary artisan would have been motivated to design and synthesize any set of six primers (*e.g.* the instant SEQ ID NO: 9-13) having the features set forth by Nagamine for amplification of the 16S rDNA sequence of taught by Yamazaki, since the *Alicyclobacillus acidoterrestris* 16S rDNA sequence was known. Furthermore, since Goto and Yamazaki identified conserved and variable regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence, an ordinary artisan would have had a reasonable expectation of success in designing the primer set suggested by the prior art of Yamazaki and Nagamine. Thus, in the absence of secondary considerations, the claimed primer set is prima facie obvious over Yamazaki in view of Nagamine and further in view of Goto.

Attention is also directed to *KSR Int'l Co. v. Teleflex Inc.* (550 U.S.____, 127 S. Ct. 1727 (2007)) where the Supreme Court determined that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103 (*KSR*, 550 U.S. at ____, 82 USPQ2d at 1397)."

In the instant case, as discussed above, an ordinary artisan would have been motivated by the teachings of Yamazaki and Nagamine to design and synthesize a set of six primers for amplifying the *Alicyclobacillus acidoterrestris* 16S rDNA. An ordinary artisan would have been motivated to design primers for amplification of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence taught by Yamazaki that were suitable for use in the more sensitive and specific LAMP method of Nagamine. Since the complete nucleotide sequence of the *Alicyclobacillus acidoterrestris* 16S rDNA was known in the art, and since conserved and variable regions of the

sequence were identified by Yamazaki and Goto, an ordinary artisan would have been presented with a finite number of regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence from which to design LAMP primers. Thus, the prior art suggested a finite number of primer sets for amplification of the *Alicyclobacillus acidoterrestris* 16S rDNA by the LAMP method of Nagamine. Since the prior art of Yamazaki and Goto identified conserved and variable regions of the *Alicyclobacillus acidoterrestris* 16S rDNA sequence and since Nagamine provided a detailed discussion of the requirements for LAMP primers, an ordinary artisan would have expected predictable results, and thus, would have had a reasonable expectation of success in obtaining a primer set (*e.g.* SEQ ID NO: 9-13) from the finite number of possibilities suggested by the prior art. Thus, the primer set of claim 4 is *prima facie* obvious in view of the combined teachings of the cited references in the absence of secondary considerations.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (Letters in Applied Microbiology (1996) 23: 350-354; cited previously) in view of Goto et al. (Journal of General Microbiology (2002) 48: 243-250; cited on an IDS) and further in view of Nagamine et al. (Molecular and Cellular Probes (2002) 16: 223-229) and further in view of Ahern (The Scientist (1995) Vol. 9, 5 printed pages).

Claim 13 is drawn to a kit comprising a strand-displacing DNA polymerase, dNTPs, a reaction buffer and the primer of claim 1 or the primer set of claim 4.

The combined teachings of Yamazaki, Nagamine, and Goto suggest the primer set of claim 4, as discussed above.

Regarding claim 13, Yamazaki teaches conducting nucleic acid amplification using a DNA polymerase, dNTPs, and reaction buffer (page 351, column 2). Likewise, Nagamine teaches conducting nucleic acid amplification using a DNA polymerase having strand displacement activity, dNTPs, and reaction buffer (page 224).

Yamazaki, Nagamine, and Goto do not teach packaging the reagents used to conduct the nucleic acid amplification reactions in a kit.

Ahern teaches that kits comprising biochemical reagents provide a means of quality control and offer practitioners in the art savings of time and money (pages 3-4).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to package a reaction buffer, dNTPs, a DNA polymerase having strand displacement activity, and the primer set suggested by the combined teachings of Yamazaki, Nagamine, and Goto in a kit. An ordinary artisan would have been motivated to do so with a reasonable expectation of success, since Ahern taught that kits comprising biochemical reagents provided a means of quality control and offered practitioners in the art savings of time and money (pages 3-4). Thus, the kit of claim 13 is *prima facie* obvious over Yamazaki in view of Nagamine and further in view of Goto and further in view of Ahern.

Conclusion

14. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amb

/Cynthia B. Wilder/
Examiner, Art Unit 1637